# UNITED STATES DISTRICT COURT WESTERN DISTRICT OF LOUISIANA LAKE CHARLES DIVISION

UNITED STATES OF AMERICA, Plaintiff	CIVIL NO
VERSUS	JUDGE
HENRY GOOLSBY, III, M.D., PATRICIA LENAE GOOLSBY, and INFINITE HEALTH INTEGRATIVE	MAGISTRATE JUDGE
MEDICINE CENTER, INC. Defendants	JURY DEMAND

### **COMPLAINT**

The United States of America brings this action to recover losses from false claims submitted to the Medicare Program by Defendants, Dr. Henry Goolsby, III ("Dr. Goolsby"), Patricia Lenae Goolsby ("Mrs. Goolsby"), and Infinite Health Integrative Medicine Center, Inc. ("Infinite Health")(collectively "Defendants") for "procedures" using an acupuncture device and falsely and fraudulently billed under Healthcare Common Procedure Coding System L8679 (implantable neurostimulator, pulse generate, any type). Medicare paid the Defendants \$313,265 for these false claims.

### THE PARTIES

1.

Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS), on behalf of the Medicare Program.

Defendant, Dr. Henry Goolsby, III, is a licensed physician and a cofounder and Chief Executive Officer of Infinite Health Integrative Medicine Center, Inc. He is a resident of Louisiana, currently residing in Slidell, Louisiana.

3.

Defendant, Patricia Lenae Goolsby, is a cofounder and Chief Operations Officer for Infinite Health Integrative Medicine Center, Inc. She is a resident of Louisiana, currently residing in Slidell, Louisiana.

4.

Defendant, Infinite Health Integrative Medicine Center, Inc., is a medical practice that specializes in age-reversal and regenerative therapies. Currently, its principal place of business is located in Metairie, LA. Previously, and during all relevant times, its principal place of business was located at 2002 W. Walnut St., Ste. 2, Lake Charles, Louisiana.

### **JURISDICTION AND VENUE**

5.

This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345. This civil action arises under the laws of the United States, and this civil action is brought by the United States as a plaintiff pursuant to the False Claims Act ("FCA").

6.

The Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. §§ 3730 and 3732(a) because Defendants can be found in and/or have transacted business within the Western District of Louisiana and may be served at any place within the United States.

Venue is proper in the Western District of Louisiana under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because the Defendants transacted business in the district. Defendants regularly conducted substantial business within the district, maintained employees and offices within the district, and/or generated significant revenue from work performed within the district.

#### THE FALSE CLAIMS ACT

8.

The FCA provides, in pertinent part, that any person who:

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
- (C) conspires to commit a violation of subparagraph (A) [or] (B...is liable to the United States Government [for statutory damages and such penalties as are allowed by law]." 31 U.S.C. §§ 3729(a).

9.

The FCA further provides that "knowing" and "knowingly"

- (A) means that a person, with respect to information—
- i. has actual knowledge of the information;
- acts in deliberate ignorance of the truth or falsity of the information; ii.
- iii. acts in reckless disregard of the truth or falsity of the information; and
- (B) requires no specific intent to defraud.
- 31 U.S.C. § 3729(b).

The FCA, 31 U.S.C. § 3729(a)(1), provides that any person who violates the Act is liable to the United States Government for three times the amount of damages which the Government sustains because of the act of that person, plus a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. See 28 C.F.R. § 85.5 (setting forth the current penalties level of not less than \$13,508 and not more than \$27,018 for violations of the FCA).

### **MEDICARE**

11.

In 1965, Congress enacted Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 et seq., to provide health insurance coverage for people 65 or older and for people with certain disabilities or afflictions. See 42 U.S.C. §§ 426, 426a.

12.

Medicare is administered by CMS, which is part of HHS. At all times relevant to this complaint, CMS contracted with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

13.

Medicare provides coverage for items and services that are reasonable and necessary to diagnose or treat an illness or injury or to improve a malformed body member. Section 1862(a)(1) of the Social Security Act. CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Ch. 16, sec. 20.

The Medicare Program consists of four parts: A, B, C, and D. As alleged herein, Defendants submitted, or caused to be submitted, false claims under Medicare Part B.

15.

Medicare Part B covers medically necessary services, including provider visits, diagnostic tools that meet accepted standards for medical practice, procedures, medical supplies and DME.

16.

For a health care provider to seek reimbursement from the Medicare Program, the provider must obtain a National Provider Identifier ("NPI") from CMS. The provider also must submit an enrollment application.

17.

Once the provider is enrolled, the provider may submit bills to the Medicare Program for services rendered to the patients. A participating provider must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 431.107(b)(1).

18.

Medicare only pays for Part B services that are actually rendered and are reasonable and medically necessary. 42 U.S.C. § 1395y(a). Part B providers must certify that services are medically necessary. 42 C.F.R. § 424.24(g)(1).

19.

To obtain reimbursement from the Medicare Program, providers submit a claim form, which is typically done electronically. In particular, providers submit CMS Form 1500 and/or its equivalent, known as the 837P form, which contains the following certifications:

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate, and complete; 2) I have familiarized myself with all applicable laws, regulations and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self- Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were incident to my professional service by my employee under my direct supervisor, except as otherwise permitted by Medicare or TRICARE . . . .

NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by the form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

20.

Among the information the provider includes on a CMS 1500 or 837P form are certain five-digit codes, including Current Procedural Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Ch. 23, § 20.7 et seq.

21.

Providing accurate CPT and HCPCS codes on claims submission forms is material to and a condition of payment for the Medicare Program. See, e.g., Medicare Learning Network Fact Sheet, Medicare Billing: 837P and Form CMS-1500.

The Medicare Program routinely denies payment to providers who bill for codes when the criteria for those codes is not actually met, including when the services are not performed or are not medically necessary.

#### FACTUAL BACKGROUND

23.

Dr. Goolsby is a physician specializing in internal medicine and oncology. He is a cofounder and CEO of Infinite Health Integrative Medicine Center, Inc.

24.

In June of 2016, Dr. Goolsby and Mrs. Goolsby co-founded Infinite Health, which was a name change from his previous practice, The Oncology and Hematology Institute of SWLA, Inc. At all relevant times, Mrs. Goolsby served as the Chief Operations Officer of Infinite Health.

25.

From November of 2018 through April of 2020, Dr. Goolsby and/or Infinite Health Integrative Medicine Center submitted claims for reimbursement to Medicare for surgically implanted neurostimulators but only applied P-Stim acupuncture devices.

26.

A P-Stim is an electric acupuncture device that is attached to the ears of the patient using two small pads. This non-covered acupuncture "service" is provided in an office setting.

27.

A National Coverage Determination ("NCD") for Acupuncture (30.3) states "acupuncture is not considered reasonable and necessary" within the meaning of Section of 1862(a)(1) of the Social Security Act (the "Act"). This is a long-standing determination and was widely known throughout the relevant time period.

28.

Some, if not all, of the devices Defendants used to perform this acupuncture service were made by a company called Stivax.

29.

The Stivax website includes a disclaimer stating "[i]t is our understanding that Medicare and some commercial insurance companies are not covering electro-acupuncture or auricular vagus nerve stimulation devices such as Stivax at this time."

30.

To circumvent this prohibition against coverage for acupuncture, Defendants billed Medicare using HCPCS L8679 in connection with the P-Stim "treatment." While the P-Stim devices typically cost between \$300 and \$500, Medicare typically reimburses between \$5,000 and \$6,500 for products coded as HCPCS L8679.

31.

HCPCS L8679 is the code for an implantable neurostimulator and pulse generator. This procedure requires the provider perform surgery by making an incision on the patient's back and placing the leads (medical wires) that deliver the stimulation into the epidural space on the spinal cord. Payment for the surgical procedure requires the service to be performed in a surgery center. When billed in an outpatient center HCPCS L8679 is non-payable.

Guidance issued by CMS and Medicare contractors on August 11, 2016, August 1, 2018, and January 29, 2020 made it clear that P-Stim and similar electro-acupuncture devices were not covered by Medicare and should not be billed as HCPCS code L8679.

33.

Starting in the November of 2018, Defendants began using the P-Stim acupuncture device. Defendants' P-Stim "treatment" was not performed at a surgery center, required no surgical implantation, and merely placed two wires on or near the patient's ears. The P-Stim "treatment," therefore, was clearly not covered by HCPCS L8679. Despite this, Defendants repeatedly billed the P-Stim "treatment" to the Medicare Program with code HCPCS L8679 by using CMS 1500 Forms containing false information and certifications.

34.

Based on Defendants' false submissions to Medicare for HCPCS L8679 for the P-Stim treatment, the Medicare Program paid Defendants between \$5,800 and \$6,500 for each "treatment."

35.

Mrs. Goolsby ordered and obtained the P-Stim devices from several sources and even sought to become a distributor of the devices.

36.

In total, Defendants were paid \$313,265 for approximately one hundred false P-Stim claims that were falsely certified as "medically necessary" and improperly submitted under HCPCS L8679 through CMS 1500 Forms or the equivalent.

The United States would not have paid any portion of the \$313,265 to the Defendants had it known Defendants were performing a P-Stim acupuncture "treatment" in an office setting rather than the surgical procedure set forth in HCPCS L8679.

### Count I

(FCA: Presentment of False Claims (31 U.S.C. § 3729(a)(1)(A))

38.

The United States incorporates by reference Paragraphs 1 through 37 above as if fully set forth in this Paragraph.

39.

As detailed above, Defendants knowingly presented, or caused to be presented, materially false and fraudulent claims for payment or approval to the United States, including claims for reimbursement by the Medicare Program that were false and fraudulent because they (i) were for services for which the Medicare Program does not reimburse; and/or (ii) were not medically necessary.

40.

As detailed above, the Medicare Program would not otherwise have paid for these false and fraudulent claims.

41.

Defendants presented or caused to be presented these claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

Defendants are liable to the United States for damages in an amount to be determined at trial, but not less than \$313,265. in single damages, trebled, as well as civil penalties of at least \$13,946 and not more than \$27,894 for each claim.

## **Count II**

(FCA: Making or Using False Statements Material to a False Claim (31 U.S.C. § 3729(a)(1)(B))

43.

The United States incorporates by reference Paragraphs 1 through 37 above as if fully set forth in this Paragraph.

44.

As detailed above, Defendants knowingly made, used, or caused to be made or used, false records or statements, which included false certifications and representations on forms CMS 1500 to obtain approval for and payment by the United States for false or fraudulent claims as detailed above.

45.

Defendants' false certifications and representations were made for the purpose of ensuring that the Medicare Program paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of Defendants' statements and actions.

46.

The false certifications and representations made or caused to be made by Defendants were material to the payment of the false claims by the United States.

Said false records or statements were made with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

48.

Defendants are liable to the United States for damages in an amount to be determined at trial, but not less than \$313,265 in single damages, trebled, as well as civil penalties of at least \$13,946 and not more than \$27,894 for each claim.

#### **Count III**

### (Payment by Mistake)

49.

The United States incorporates by reference Paragraphs 1 through 37 above as if fully set forth in this Paragraph.

50.

The United States paid Defendants, either directly or indirectly, for claims submitted by Defendants for services that were (i) not medically necessary; and/or (ii) did not otherwise satisfy the requirements of the Medicare Program, without knowledge of material facts, and under the mistaken belief that Defendants were entitled to receive payment for such claims.

51.

The mistaken belief of the United States was material to their decision to pay Defendant for such claims.

The United States reasonably relied on Defendants' submission of claims that they believed were accurate, complete, and truthful, in accordance with the express requirements of the Medicare Program.

53.

The United States has been damaged as a result of this mistaken payment, and the Defendants are thus liable to account and pay to the United States such amounts, which are to be determined at trial.

#### **Count IV**

### (Unjust Enrichment)

54.

The United States incorporates by reference Paragraphs 1 through 37 above as if fully set forth in this Paragraph.

55.

By retaining monies and profits received from services that were not reimbursable, Defendants retained money that was the property of the Medicare Program, to which they are not entitled.

56.

The United States seeks the recovery of all funds paid by the Medicare Program by which Defendants have been unjustly enriched, including profits unlawfully earned for acupuncture that was medically unnecessary and not accurately identified.

As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the United States in an amount to be determined and which, under the circumstances, in equity and good conscience, should be returned to the United States.

## **PRAYER FOR RELIEF**

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants, jointly and severally, as follows:

On the First and Second Counts under the FCA for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such relief as may be just and proper.

On the Third Count for payment by mistake, for the amounts the United States paid by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

On the Fourth Count for unjust enrichment, for the amounts by which Defendants were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

#### **DEMAND FOR A JURY TRIAL**

The United States demands a jury trial.

This 10 day of January, 2025.

Respectfully submitted,

BRANDON B. BROWN United States Attorney

BY: <u>s/Melissa L. Theriot</u>

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